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Analysis of Clinical Outcomes and Cost-Effectiveness of Neuromuscular Blocking Drug Reversal in Patients with Obstructive Sleep Apnea

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by

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Abstract

Non-depolarizing neuromuscular blockers are used during many surgical procedures to induce muscle relaxation for tracheal intubation and improve surgical conditions for surgeons. The use of these medications requires an agent to be given to fully reverse the effects of the neuromuscular blocking drug. Historically, neostigmine has widely been used as the primary reversal agent. However, sugammadex, a recently FDA approved drug, is also available for the reversal of common neuromuscular blocking drugs, rocuronium and vecuronium. In the literature, sugammadex is widely regarded as a clinically superior reversal agent. But its use is commonly limited to emergent situations due to the high price associated with the drug. A risk associated with reversal agents is incomplete recovery from the neuromuscular blockade that can lead to postoperative pulmonary complications. Patients with certain comorbidities are at higher risk for postoperative pulmonary complications (PPCs). Patients with obstructive sleep apnea already struggle with airway obstruction and may be at higher risk for adverse outcomes after the use of neuromuscular blocking agents (NMBAs). Therefore, this project seeks to provide evidence-based recommendations for NMBA reversal in patients diagnosed with or identified as at risk for OSA through a literature search and synthesis. Therefore, the project developed evidence-based practice recommendations utilizing the John Hopkins Nursing Evidence-Based Practice Model by asking a practice question, evaluating, and translating findings into practice. The project will also outline a plan for implementation and evaluation of outcomes such as cost effectiveness and clinical outcomes.

Problem Identification

Introduction of Problem

Neuromuscular blocking agents (NMBAs) are an essential part of anesthesia care and management in the operating room. NMBAs are used to facilitate tracheal intubation and provide optimal surgical conditions. The use of NMBAs requires the administration of a reversal agent such as sugammadex or neostigmine. However, a risk of using NMBAs is incomplete recovery from the reversal of the medication, also known as residual neuromuscular blockade. Residual neuromuscular blockade can be benign or lead to catastrophic events, most known as postoperative pulmonary complications (PPCs). A population most at risk for PPCs is patients with obstructive sleep apnea (OSA). Effective use of neuromuscular blockade reversal medications may reduce adverse outcomes for patients with OSA.

Background

There are two types of neuromuscular blockers—depolarizing and non-depolarizing. Depolarizing neuromuscular blocking agents, such as succinylcholine, mechanism of action is continuous depolarization of the postsynaptic neuromuscular junction (NMJ) resulting in short-term muscle paralysis. Depolarizing neuromuscular blockers do not require the use of a reversal agent due to the rapid breakdown of the drug by pseudocholinesterase. Non-depolarizers work by competitively inhibiting post-junctional nicotinic Acetylcholine (ACh) receptors in the NMJ. The binding of non-depolarizing NMBAs prevents the depolarization of the NMJ resulting in flaccid paralysis (Cook & Simons, 2021).

Non-depolarizers are categorized based on their chemical structures into amino-steroidal and benzylisoquinoliniums. Benzylisoquinoliniums such as mivacurium, atracurium, and cisatracurium, are eliminated via organ independent degradation. Due to the differences in

chemical structure, benzylisoquinoliniums' effects can only be reversed with the administration of neostigmine. The two amino-steroidal agents—rocuronium and vecuronium, are dependent on organs for metabolism and excretion of the medication. Rocuronium's onset is 1-2 minutes, the peak is 90 seconds, and the duration is 20-35 minutes. The onset and peak of vecuronium are 3-5 minutes and the duration of action is 20-35 minutes (Vargo Anesthesia Inc, 2021). The unique chemical structure of rocuronium and vecuronium allows for reversal with either neostigmine or sugammadex.

Rocuronium and vecuronium bind competitively to the ACh receptors and can be overcome by the administration of acetylcholinesterase inhibitors such as neostigmine. Neostigmine works by inhibiting the breakdown of acetylcholine thus increasing the concentration of ACh at the NMJ. ACh then outnumbers the rocuronium or vecuronium and allows for depolarization to occur. The onset of neostigmine is 1-5 minutes, peaking at 7-14 minutes and lasting 30-60 minutes (Vargo Anesthesia Inc, 2021). The concentration of ACh not only increases at the NMJ but systemically. The increased concentration of ACh systemically directly leads to a plethora of side effects such as bradycardia, bronchoconstriction, salivation, and increased gastric motility. Neostigmine has also been associated with an increase in postoperative nausea and vomiting (PONV). The concomitant administration of glycopyrrolate, an anti-cholinergic, is needed to reduce these side effects. Glycopyrrolate antagonizes acetylcholine at muscarinic receptor sites, thus offsetting systemic detrimental side effects of neostigmine. Glycopyrrolate does not affect acetylcholine at nicotinic receptor sites, such as in the NMJ. Another reversal agent for amino-steroidal NMBAs is sugammadex. Sugammadex works by irreversibly binding to the amino-steroidal NMBAs, rocuronium and vecuronium, and is eliminated in the urine. Sugammadex has potential side effects of anaphylaxis, bradycardia,

PONV, and reduces the effectiveness of hormonal contraceptives. Sugammadex onset is 3 minutes, and the half-life is 2 hours (FDA, 2015).

Significance Related to Nurse Anesthesia

A risk of using NMBAs is residual neuromuscular blockade leading to PPCs, and patients with OSA are at an increased risk for these events. PPCs include any unanticipated hypoxemia, hypoventilation, or upper airway obstruction requiring an active and specific intervention. Obstructive sleep apnea (OSA) is identified in the literature as a condition that is associated with pulmonary complications in the immediate postoperative period (Li et al., 2021). OSA is defined as a "breathing disorder, prevalent in the obese population, distinguished by periodic, partial, or complete obstruction of the upper airway during sleep" (Nagelhout & Elisha, 2018). Patients at risk for OSA are often identified with screening tools such as the STOP-Bang Questionnaire. The questionnaire includes an assessment of snoring, tiredness, observed apnea, high blood pressure, body mass index (BMI), age, neck circumference, and gender.

The risk of residual neuromuscular blockade associated with rocuronium or vecuronium administration and the possibility of pulmonary complications in patients with OSA necessitates total and prompt reversal of neuromuscular blockade. Before Food and Drug Administrations (FDA) approval of sugammadex in 2015, neostigmine was the only option for the reversal of rocuronium and vecuronium. Sugammadex now offers an alternative to rocuronium and vecuronium reversal. The upfront cost associated with sugammadex is often cited as the reason for the uninhibited use of the medication (Carron et al., 2017).

Raval et al. (2020) evaluated 20 randomized control trials (RCTs) and found at two minutes after sugammadex administration residual neuromuscular blockade was 19.8% and declined to 2.8% at six minutes versus neostigmine of 100% and 82% respectively for a

moderate block. The same study also found that residual neuromuscular blockade was reduced to 1% fifteen minutes after administration of sugammadex for a deep block while neostigmine remained at or above 95% for 60 minutes after administration. Kheterpal et al. (2020) found a 30% reduction in pulmonary complications including a 47% reduced risk of pneumonia and a 55% reduced risk of respiratory failure associated with sugammadex when compared to neostigmine.

It is important to consider the clinical outcomes associated with each reversal medication while considering patient safety and the overall cost-effectiveness for the hospital system. The average cost associated with a PPC, the amount of time in the post anesthesia recovery care unit (PACU), and the operating room (OR) turnover time should be considered in addition to the upfront cost of each medication. The purpose of the project is to explore the differences in clinical outcomes and cost-effectiveness of neostigmine and sugammadex in OSA patients undergoing surgery.

PICO Question

Utilizing our previously described problem, a PICO formatted question was derived to guide a literature search. The PICO format will be used to provide strategic key search terms to obtain the best evidence in this project. The four components of a PICO question include "population of interest [P], intervention of interest [I], comparison of interest [C], and outcome of interest [O]" (Mazurek-Melnyk & Fineout-Overholt, 2019). In (P) surgical patients who are diagnosed with or identified as high risk for OSA, (I) how does the use of sugammadex for reversal of amino-steroidal non-depolarizing blockers (C) compared to neostigmine (O) affect postoperative patient outcomes and cost-effectiveness related to postoperative pulmonary complications and time in PACU?

Projective Objectives

The purpose of this project is the development of evidence-based practice recommendations with a plan for implementation and evaluation of these recommendations. From this purpose, the objectives for this project are listed below.

1) Synthesize evidence from the literature search for use of sugammadex or neostigmine for reversal of NMBAs.
2) Develop evidence-based practice recommendations for the reversal of rocuronium and vecuronium in patients at risk for OSA.
3) Develop a comprehensive plan to implement, monitor, and adjust these recommendations which include a cost-benefit analysis and evaluation of patient outcomes for patients with OSA.

Literature Search

Project Question and Search Terms

To investigate the aforementioned clinical outcomes and cost-effectiveness, a literature review was conducted utilizing the above PICO question. The international electronic databases that were used were Cochrane Database of Systematic Reviews (CDSR), Medline, and the Otterbein University library database. Key search terms were broken down by each aspect of the PICO(T) question. For the patient population (P), the search terms: surgical patients and obstructive sleep apnea were utilized. To explore the intervention (I), search terms: sugammadex, neostigmine, neuromuscular blocking agents, rocuronium, vecuronium, and glycopyrrolate were used. The search terms focused on the outcomes (O) included: postoperative patient outcomes, cost, cost-effectiveness, postoperative pulmonary complications, reintubation, aspiration, residual neuromuscular blockade, time, and time in PACU. The main Boolean

operator used was “and” to connect these keywords. All search results were narrowed to peer-reviewed literature, conducted in or translated to English, and published within the last decade. Organization and summarization of the literature articles were completed utilizing a level of evidence synthesis table (Appendix A).

Postoperative Pulmonary Complications and Obstructive Sleep Apnea

To better understand how neuromuscular blocking agents and their residual effects can be detrimental to patients with obstructive sleep apnea (OSA), obstructive sleep apnea must be defined and related to PPCs according to the literature. According to Nagelhout & Elisha (2018), OSA is the result of relaxation of pharyngeal muscle that subsequently causes airway obstruction during sleep. The prevalence of OSA has continued to rise within the United States due to the obesity pandemic (Chung & Mokhlesi, 2014). It is estimated that up to 24% of males and 9% of females have OSA (Nagelhout & Elisha, 2018). One of the primary risk factors for developing OSA is obesity (Nagelhout & Elisha, 2018).

The incidence of encountering surgical patients with OSA is continuing to increase as the obesity epidemic and the overall number of surgeries per year increases (Chung & Mokhlesi, 2014). This is of the utmost importance for anesthesia providers due to the mechanism of action of many of the drugs administered peri-operatively, including neuromuscular blocking agents, narcotics, and sedatives (Chung & Mokhlesi, 2014). Neuromuscular blocking drugs (NMBDs) act directly on pharyngeal musculature, causing varying degrees of weakness that results in mechanical obstruction of the airway and impairs effective ventilation (Miskovic & Lumb, 2017). The residual effects of NMBDs leftover from reversal with sugammadex or neostigmine can result in postoperative residual blockade (PORB) and concurrent pulmonary complications (Miskovic & Lumb, 2017). These effects are even more prevalent in surgical patients with OSA

and can be seen even if clinically adequate recovery appears achieved (Miskovic & Lumb, 2017).

Surgical patients with OSA who receive a NMBD and subsequent reversal with sugammadex or neostigmine are at higher risk of developing PPCs compared to non-OSA patients (Kaw et al., 2012). Kaw et al. (2012) conducted a meta-analysis of thirteen studies involving nearly 4,000 patients that concluded that surgical patients with OSA were at a higher risk of "postoperative desaturation, respiratory failure, postoperative cardiac events, and ICU transfers." The systematic review by Hafeez et al. (2018) concluded that OSA was an independent risk factor for developing a PPC and the occurrence of a PPC increased overall mortality. A multi-center study by Fernandez-Bustamante et al. (2017) concluded that even mild PPCs, such as supplemental oxygen, were strongly associated with "increased early postoperative mortality, ICU admission, and length of stay (ICU and hospital)." The authors go on to state that even mild PPCs can hinder patient outcomes and subsequently increase the cost of care and thus attention and intervention should be implemented to improve clinical and financial outcomes (Fernandez-Bustamante et al., 2017).

Not only are PPCs associated with an increase in mortality, but also an increased cost as additional interventions may be needed and length of stay extended (Miskovic & Lumb, 2017). Miskovic & Lumb (2017) found that pneumonia and respiratory failure because of PPCs contributed to a roughly 45% increase in overall cost. To highlight the magnitude of PPCs and associated cost, Fleisher & Linde-Zwirble (2014) reviewed 45,969 records of discharged gastrointestinal surgical patients and found that PPCs were present in 22% of cases and averaged an additional cost of $25,498.

Screening for OSA

As discussed above, OSA places a patient at higher risk for respiratory complications following a surgical procedure. However, the majority of surgical patients with OSA remain undiagnosed at the time of surgery (Nagappa et al., 2015). It is important to identify these patients during the pre-operative period so that they can be appropriately monitored and managed throughout the perioperative experience. While the gold standard for diagnosis of OSA is an overnight polysomnogram, this is not an option at the time a patient is presenting for a procedure. The STOP-Bang questionnaire is an assessment tool that can be completed in minutes and utilized to identify patients who are at risk for sleep apnea. The tool includes four subjective questions about snoring, tiredness, observed apnea, and high blood pressure. The other four items scored include demographics such as BMI greater than 35 kg/m2, age over 50, neck circumference greater than 40 cm, and male gender. Each item is answered yes or no and a score less than three is a low risk while greater than or equal to three is high risk (Nagelhout & Elisha, 2018).

Nagappa et al. (2015) explored the validity of the STOP-Bang screening tool through a systematic review and meta-analysis. The high-level review and analysis included seventeen studies including 9,206 patients. Of the seventeen studies found, all of the studies used a polysomnogram test for confirmation of obstructive sleep apnea initially identified by a STOP-Bang score. Overall, the study found the probability of moderate to severe obstructive sleep apnea increased as the STOP-Bang score increased (Nagappa et al., 2015).

Clinical Outcomes of Sugammadex versus Neostigmine as Reversal Agents

PPCs due to residual neuromuscular blockade are always a risk when NMBDs are administered. The NMBDs focused on in this project are the amino-steroidal neuromuscular

blocking drugs, rocuronium and vecuronium. After administration of rocuronium or vecuronium, sugammadex or neostigmine with glycopyrrolate must be given to reverse the paralytic effects and decrease the likelihood of residual neuromuscular blockade that can lead to PPCs (Brueckman et al., 2015). As stated above, Miskovic & Lumb (2017) found that even if appropriate clinical indicators demonstrate adequate reversal, residual neuromuscular blockade may still exist postoperatively leading to PPCs. Furthermore, surgical patients with OSA are even more sensitive to the residual effects of rocuronium and vecuronium, potentially leading to mild or catastrophic PPCs (Li et al., 2021). As evidenced above, PPCs not only lead to an increase in mortality but also the overall cost of healthcare (Fernandez-Bustamante, 2018). Thus, the literature search aims to elucidate the most up-to-date evidence-based practice regarding sugammadex and neostigmine and associated clinical outcomes and cost-effectiveness.

One of the most prominent studies involving sugammadex and neostigmine is the STRONGER trial by Kheterpal et al. (2020). The current mainstay practice in many facilities and by anesthesia providers in the United States is the administration of neostigmine over sugammadex due to familiarity with neostigmine and lower cost. The STRONGER study challenges the inhibited use of sugammadex in comparison with neostigmine due to familiarity and cost-effectiveness. The extensive, multicenter observational matched-cohort study consisted of 12 hospitals involving 45,712 patients receiving either sugammadex or neostigmine. The primary composite recorded was PPCs feasibly related to neuromuscular blocking agents rocuronium or vecuronium. PPCs in this study were defined as pneumonia, respiratory failure, or other major pulmonary complications (Kheterpal et al., 2020). Perioperative variables were noted to be extremely balanced throughout both the sugammadex group and neostigmine group concerning the patient, procedure, and intraoperative care factors. The trial results demonstrated

a 30-50% decreased risk of pneumonia and respiratory failure with the use of sugammadex compared to neostigmine (Kheterpal et al., 2020). In terms of cost-effectiveness, Kheterpal et al. (2020) estimate that the average cost of a major pulmonary complication as described in this study equates to nearly $100,000.

Our most relevant and highest level of evidence study came from a systematic review conducted in 2018 investigating the postoperative pulmonary complications associated with neuromuscular blocking drugs or reversal agents in patients with obstructive sleep apnea (Hafeez et al., 2018). “Postoperative complications with neuromuscular blocking drugs and/or reversal agents in obstructive sleep apnea patients” initially included 4,123 studies, but only five studies were permitted due to stringent inclusion criteria. Of these five studies, totaling 1,126 patients, two studies were randomized controlled trials (RCT) and three were observational studies. Hafeez et al. (2018) recommend that higher-quality studies are needed to clarify the effects of sugammadex and neostigmine on postoperative pulmonary complications in patients with OSA. The STRONGER trial and this systematic review involving multiple studies agree that sugammadex appears to be superior to neostigmine in preventing PPCs. Hafeez et al. (2018) suggested that higher-quality studies needed to be performed, during which the STRONGER trial was still being completed.

Unal et al. (2020) published a study in the Turkish Journal of Anaesthesiology & Reanimation that focused on outcomes such as train of four (a tool used to monitor neuromuscular blockade depth), operating room time, post-anesthesia care unit (PACU) time, postoperative respiratory complications, costs related to neuromuscular block reversal and follow-up and treatment complications. The study involved patients undergoing surgery with a diagnosis of OSA. The results of the study demonstrated a decreased incidence of PPCs in the

sugammadex group along with a higher reversal cost compared to the neostigmine group (Unal et al., 2020). Although the reversal cost was higher in the sugammadex group, the overall follow-up and treatment costs for neostigmine vastly outweighed the cost of sugammadex (Unal et al., 2020). Although the results seem promising for sugammadex, major limitations exist within this study such as: only rocuronium was used, a small sample size of 74 patients, and the patient's American Society of Anesthesiologists (ASA) physical status was I or II which does not seem accurate if the patients have a history of OSA already (Unal et al., 2020).

A meta-analysis by Carron et al. (2017) explored patient discharge readiness between sugammadex and neostigmine after neuromuscular blockade reversal. Carron et al. (2017) highlighted the fact that sugammadex is known to be faster and more effective at reversing deeper blockades than neostigmine. The authors argued that prior studies suggesting otherwise either based sugammadex dosing on qualitative monitoring instead of the recommended quantitative monitoring leading to the administration of an inadequate dose. Carron et al. (2017) state that these prior studies reflect "inappropriate use rather than failure of the drug." Thus, this study performed a meta-analysis involving 518 patients from six studies where the time from operating room (OR) to PACU was tracked, along with time from PACU to the surgical ward. The results of this study concluded that sugammadex was superior at discharging patients from the OR to the PACU but did not show superiority for discharge from PACU to the surgical ward (Carron et al., 2017). Although this meta-analysis did not reflect superior patient clinical outcomes such as reduced PPCs, it did reflect a faster discharge from the OR which would lead to faster turn-over time and increased cost-effectiveness. Carron et al. (2016) is a retrospective analysis by the same authors who conducted the meta-analysis in 2017. In this retrospective analysis, Carron et al. (2016) investigated clinical outcomes and cost-effectiveness of

sugammadex at their own University Hospital of Padova in Italy. The most commonly occurring PPC was difficulty weaning from the ventilator, hypoxemia, respiratory distress, and respiratory failure (Carron et al., 2016). Sugammadex demonstrated a reduced number of PPCs in comparison to neostigmine. In addition to a reduced number of PPCs, the sugammadex group had 1 intensive care unit (ICU) admission compared to the neostigmine group which had 10 (Carron et al., 2016). The sugammadex group had an average recovery room stay of 56 minutes while the neostigmine group had an average recovery room stay of 103 minutes. Overall, Carron et al. (2016) concluded that neuromuscular blockade that was reversed with sugammadex demonstrated a reduced risk of residual neuromuscular blockade and subsequence PPCs.

Cost Associated with Sugammadex versus Neostigmine as Reversal Agents

While patient safety and the clinical outcomes associated with each reversal agent take the highest priority when recommendations are created for the use of reversal agents, hospitals must also consider the costs connected with each drug and the subsequent costs related to complications or lack thereof. Train of four (TOF) monitoring should be utilized to assess the degree of neuromuscular blockade throughout the surgery and immediately before the administration of a reversal agent (Nagelhout & Elisha, 2018). A peripheral nerve stimulator, or train of four, delivers four electrical impulses to the patient and the user counts the number of twitches elicited. The dose of reversal medication is then calculated based on the number of twitches and the patient's body weight (Flood et al., 2014).

The dose of neostigmine is 0.02-0.08 milligrams (mg)/kilogram (kg) dependent on the number of twitches elicited. For two of four twitches with fade, 0.07 mg/kg should be administered. For four of four twitches with fade 0.04 mg/kg should be administered (Vargo Anesthesia Inc, 2021). As discussed above, glycopyrrolate must be administered concomitantly

with neostigmine to offset the side effects. For every 1 mg of neostigmine given, 0.2 mg of glycopyrrolate should be administered. The average wholesale price of neostigmine is $22.03 for a 10 mg/10 milliliter (mL) multi-dose vial and $20.81 for a 5 mg/10 mL multi-dose vial. The average wholesale price for glycopyrrolate is $8.40 for a 0.2 mg/1 mL single-dose vial and $16.68 for a 0.4 mg/2 mL single-dose vial (Deyhim et al., 2020).

Sugammadex dosing is also based on the number of elicited twitches and the patient's weight. If two of four twitches are elicited, 2mg/kg of sugammadex should be administered. Sugammadex can be used if no twitches are elicited at a dose of 4mg/kg and in an emergency after an intubating dose of rocuronium has been administered at 16 mg/kg. Sugammadex does not require any other drug to be administered with it (Vargo Anesthesia Inc, 2021). The average wholesale price of sugammadex is $219.24 for a single-dose 500 mg/5mL vial and $119.69 for a single-dose 200 mg/2 mL vial (Deyhim et al., 2020).

Along with the upfront price of reversal agents, the costs associated with time for reversal and adverse events associated with the medication must also be evaluated. Hurford et al. (2020) estimated the direct cost for OR time is $32.49 per minute, postoperative mechanical ventilation at $2,631.85 per day, and the cost associated with PONV to be $98.62. Ultimately, the net cost for sugammadex was found to be $225 lower than the net costs associated with reversal with neostigmine and glycopyrrolate. The largest cost savings for sugammadex was attributed to a reduction in non-operative OR time (Hurford et al., 2020).

To summarize, this literature search, review, and synthesis offered promising evidence-based support of the use of sugammadex over neostigmine to improve clinical outcomes and cost-effectiveness in surgical patients with OSA. An overwhelming majority of studies highlighted the superiority of sugammadex over neostigmine in terms of residual neuromuscular

blockade and subsequent PPCs. Regarding surgical patients with OSA, it is safe to say that the literature unanimously elucidates patients with OSA are considered an "at-risk" population for PPCs after administration of a NMBD (Hafeez et al., 2018). Not only does sugammadex provide clinical outcome benefits by reducing incidences of PPCs, but the drug also demonstrates an ability to be cost-effective simultaneously (Carron et al., 2016).

Model Used for Project Framework

The theoretical framework utilized for this project was the John Hopkins Nursing Evidence-Based Practice model (JHNEBP) (Dang & Dearholt, 2022) (Appendix B). Listed in Appendix B is the "Copyright Permission Form" completed through John Hopkins Medicine Institution that granted access to use the evidence-based practice model and tools. This model was chosen due to its ability to solve clinical decision-making problems with evidence-based practice (Dang & Dearholt, 2022). Additionally, by utilizing the signature three-step process called PET, users can efficiently incorporate the most up-to-date practices into patient care (Dang & Dearholt, 2022). The three-step process includes: asking a practice question (P), synthesizing the evidence (E), and translating the evidence into best practice (T) (Dang & Dearholt, 2022).

The first phase of the model included identifying the practice question utilizing a six-step process (Dang & Dearholt, 2022). First, a team was developed that consisted of two DNP students, the project advisor, pharmacy, and the quality control department within the organization. Second, the presence of inconsistency within the current clinical practice was identified to define the problem. Sugammadex and neostigmine are both used to reverse the effects of neuromuscular blocking agents (Nagelhout & Elisha, 2018). Each drug has a differing mechanism of action and subsequent side effects associated with its use. No clear policies or

guidelines are in place to support the use of one drug over the other. Additionally, certain at-risk populations can be predisposed to the side effects of neuromuscular blockade reversal, such as patients with obstructive sleep apnea (Miskovic & Lumb, 2017). Third, the following evidence-based practice (EBP) question was constructed: How do the clinical outcomes and cost-effectiveness of sugammadex compare to neostigmine with glycopyrrolate in surgical patients with obstructive sleep apnea? Fourth, the stakeholders associated with this project were identified and included patients, certified registered nurse anesthetists, (CRNAs), anesthesiologists, pharmacy, quality control team, hospital administration, and the organization. Fifth, the two partnered DNP students determined leadership for the project and met weekly to discuss project goals, visions, knowledge, and overall direction. Last, quarterly meetings were scheduled and held between the DNP students and project advisor to facilitate progressive project completion and success.

The second phase of the model will include synthesizing the evidence and consists of a five-step process (Dang & Dearholt, 2022). First, internal evidence will be collected through the quality control department that monitors for pre-determined quality goals throughout different departments. Specifically, data on postoperative pulmonary complications will be gathered. External evidence will be collected by utilizing a comprehensive literature search that will be synthesized. Second, Appendix A contains the level of evidence synthesis and outcomes table. Steps 9 and 10 (third and fourth in the 5 step process for this phase) were demonstrated by the evidence showing a strong correlation between postoperative pulmonary complications (PPCs) and patients with obstructive sleep apnea. Additionally, the evidence overwhelmingly supported the use of sugammadex over neostigmine with glycopyrrolate when reversing neuromuscular blocking agents in terms of clinical outcomes and cost-effectiveness. For completeness, Hafeez

et al. (2017) is a meta-analysis that concluded that sugammadex did demonstrate some evidence of being superior but recommended additional high-quality studies. Since then, Kheterpal et al. (2020) conducted an extensive trial that demonstrated significantly lower rates of PPCs associated with the use of sugammadex. Lastly, recommendations were developed for this practice change (Appendix D).

Phase three involves translating the evidence into project implementation (Dang & Dearholt, 2022). The most feasible project implementation option is to conduct an organizational assessment that monitors the appropriate outcomes and data. First, organizational access to quality control data will need to be obtained. Secondly, an organizational assessment will be conducted that investigates the project's focus involving surgical patients with OSA, the use of sugammadex or neostigmine, and the associated rate of PPCs. Dissemination of the results of the organizational assessment will be provided to the appropriate stakeholders and departments along with the external evidence gathered throughout multiple databases.

Recommendations

Based on the information gathered from the literature search presented above, the use of sugammadex for reversal of rocuronium or vecuronium in patients with sleep apnea decreased the occurrence of PPCs. Therefore, the following recommendations for neuromuscular reversal should be considered: A formatted document can be found as Appendix D.

1. ***Every surgical patient should be screened for sleep apnea with the STOP-Bang screening tool during the pre-operative period.***

- Patients with obstructive sleep apnea often remain undiagnosed at the time of arrival for their procedure. It is important to identify these patients early in the

perioperative experience so that they can be treated and monitored appropriately. Therefore, each patient screened for sleep apnea preoperatively.

2. ***A patient identified as at risk for obstructive sleep apnea, as identified by a STOP-Bang score greater than 3, or with a previous diagnosis of sleep apnea should be reversed with sugammadex.***

- A literature review revealed a higher incidence of pulmonary complications for patients with obstructive sleep apnea. The literature review also revealed fewer postoperative complications when these patients were reversed with sugammadex. Therefore, patients diagnosed with or identified as at risk for obstructive sleep apnea should be reversed with sugammadex to decrease the incidence of postoperative complications. The dosing of sugammadex should follow the manufacturer's guidelines.

3. ***If patient scores less than 3 on STOP Bang scale, choice of reversal agent should be deferred to clinician judgement with consideration of other patient comorbidities.***

- Although sugammadex is recognized clinically as the superior reversal agent in the literature, its use should not go uninhibited. As stated above, sugammadex is recommended as the reversal agent of choice in patients with a diagnosis of OSA or a STOP-BANG score of 3 or greater to reduce the likelihood of PPCs in this susceptible population. In populations who are not at an increased risk of PPCs, and received either rocuronium or vecuronium, neostigmine should still be considered if appropriate (Cammu, 2018). Additionally, patient comorbidities should be evaluated and the risk and benefit of administering sugammadex or neostigmine should be performed on a case-by-case basis (Cammu, 2018).

Comprehensive Plan for Enactment of Recommendations

In collaboration with the project team leader and team members, it was determined the project does not need IRB approval as the project does not involve human subjects. The IRB exemption can be located in Appendix C. This project will include retrospective quantitative data that will be gathered by the DNP students after acquiring the appropriate access to the data from the organization. After obtaining approval, the retrospective quantitative data will be acquired and organized to reflect the presence of a clinical problem. For the purpose of this project, an unidentified Midwest level 1 trauma center will be the organization of focus.

The project team members have constructed a plan for future implementation within an organization. To implement this project in the future, the project team will first perform a detailed chart audit involving a retrospective analysis of all surgical patients with a diagnosis of OSA or a STOP-BANG score of 3 or greater who also received rocuronium or vecuronium. The specific data points that will need to be collected are: which reversal agent was given and the amount, time from reversal agent administration to OR exit, time in PACU, reintubations in PACU/OR, aspiration pneumonia diagnosis within 48 hours of surgery, oxygen desaturation below 90% after extubation until PACU discharge, and overall length of stay (LOS) if a PPC occurred. Second, a thorough and complete literature search, such as the one completed above, will need to be performed so that the appropriate recommendations can be construed. The findings from the initial chart audit should be organized and composed into an easy-to-read graphic. Next, analyze and synthesize the literature search and summarize the cost-benefit analysis so the information can be displayed to the appropriate key stakeholders and committees

within the facility. Once approved, begin educating the appropriate departments on the recommendations during staff meetings, through lamented educational sheets and email.

Cost-Benefit Analysis

A cost-benefit analysis can be used to evaluate the financial implications of a decision. As previously mentioned, the up-front cost associated with purchasing sugammadex is often cited as the reason for reserving the use of the medication for emergencies. A cost-benefit analysis of neostigmine and sugammadex should be performed to determine the most cost-effective method for reversing neuromuscular blockade in patients with OSA.

The information from the chart audit should be condensed and used to complete the cost-benefit analysis. The average time from reversal administration to OR exit, time in PACU, number of adverse events, and the length of stay associated with an adverse event should all be taken into consideration for each medication. Using the information presented in the literature search section above, the up-front cost of the medications should be compared with the cost of the average time from reversal administration to OR exit, average PACU time, associated adverse events, and additional length of stay. The drug found to be associated with the overall lowest cost, after comparing the upfront cost to associated costs, should be considered the most cost-effective.

It is also important to consider billing and reimbursement from insurance companies and/or Medicare/Medicaid. At the hospital of interest, the patient is charged for medications that are charted. Some hospitals may have a universal charge for all anesthesia medications. It is important to know how the medications are billed for when completing the cost-benefit analysis. It is also important to consider legal costs that may be associated with adverse events related to neuromuscular blockade reversal administration. The legal costs may not be captured in the 1-

year audits, but they should be captured in the 3 and 5-year audits. While litigation costs may be delayed, they can be significant and are necessary to include for a complete analysis. Once completed, the findings from the cost-benefit analysis should be included in the presentation to key stakeholders.

Timeline

The timeline for the project leaders to implement the developed recommendations at the specified facility will occur over a period of 1 year. Initially, education will need to be presented to the following key stakeholders: anesthesiologists, certified registered nurse anesthetists, post-anesthesia care unit nurses and unit managers, operating room pharmacists, and the appropriate quality department at the facility. The project leaders will need to conduct in-person meetings with each department so that the recommendations can be enacted appropriately. The first week of rolling out the project will consist of in-person meetings with the anesthesia department, PACU, and pharmacy. During that same week, lamented educational sheets will be dispersed in every operating room and procedural area where general anesthesia occurs. Pharmacy will need to coordinate efforts to ensure each Pyxis is stocked with sugammadex during this first week of the rollout. The PACU nurse manager and nurses will be informed of what specific clinical data to monitor for and document appropriately. The quality department will monitor for sentinel events and adherence to the recommendations so that an accurate clinical and cost-benefit analysis can be completed.

After the initial rollout of the recommendations, the project leaders will then focus their efforts on maintaining compliance with the recommendations and reminders. After 1 year has passed, the project leaders will conduct a second retrospective chart audit from the second week of project rollout up to the 1-year mark. The aforementioned data points will be collected again

along with compliance with the recommendations gathered by the quality department. The data points will be organized and compared to the previous data points collected in the first chart audit to display the project's results thus far.

If the project recommendations fail to display a reduction in PPCs or cost after 1 year, the recommendations will be discontinued, and the provider's preference will be encouraged. Further monitoring will be conducted by the project leaders at 3- and 5-year time intervals from the start of the project to monitor for any legal ramifications associated with adverse events related to PPCs.

Budget

The budget for the project should include expected incurred expenses for the rollout and monitoring of the recommendations. The main expense will be acquiring the appropriate amount of sugammadex vials so that every surgical patient with OSA who receives a non-depolarizing neuromuscular blocking agent can be reversed with sugammadex. The average wholesale price of sugammadex is $219.24 for a single-dose 500 mg/5mL vial and $119.69 for a single-dose 200 mg/2 mL vial (Deyhim et al., 2020). The occurrence of OSA is hard to pinpoint but can be estimated to be around 20% in the general population (Senaratna et al., 2016). Thus, if the data is extrapolated to the number of surgeries performed daily at the unidentified Midwest level 1 trauma center, we can conclude that a safe number of sugammadex vials to have available daily is 50. The 50 vials will be divided into 40 vials of 200mg and 10 vials of 500mg. Thus, the total cost of the daily sugammadex budget is $6,980. This sum will not be spent daily due to the usage of sugammadex being tracked thereby ensuring that a surplus is not purchased.

A meeting with the pharmacy may be necessary to discuss the anticipated extra need for sugammadex and the stocking of sugammadex in the medication cart. If extra time is required

outside of a normal workday, pay for the pharmacist should also be factored into the budget. The medication cart may need to be rearranged to accommodate the extra sugammadex vials. While it is likely the sugammadex vials can be stocked in place of the neostigmine vials, larger medication carts may need to be factored into the budget if rearranging the medications is not possible. The recommendations will be presented at required weekly staff meetings and there are not any expected additional monetary expenses expected related to the dissemination of the recommendations.

Additional expenses include paper materials required to present evidence-based literature findings. A total of $50 will be allotted for material expenses. Other expenses were considered such as time conducting a literature search, and synthesis, meetings with stakeholders, and time spent developing the project paper and presentation. These time expenses will be endured by the project leaders and will not contribute to the overall monetary project budget.

Comprehensive Plan for Monitoring and Measuring Recommendations

The primary outcomes that will be monitored are time from neuromuscular blockade reversal administration to the time of operating room exit, total time in PACU, and complications associated with PORB which include re-intubation, oxygen desaturation, and aspiration pneumonia. Two secondary outcomes that would be measured if a complication from PORB occurs are the length of stay and instances of litigation related to sentinel events. Re-intubation will consist of any intubation that occurs after extubation and before discharge of PACU. The occurrence of pneumonia will be counted if it occurs within 48 hours of extubation. Oxygen desaturation will be defined as any accurately measured SpO2 saturation of less than 90% that occurs before discharge from PACU. To assess for compliance with recommendations, the audit will also collect which reversal agent was used and the dose administered. These data points can

be collected by the QA/QI department and presented to the project leaders at the appropriate time intervals.

The time intervals that would be used for this project are 1, 3, and 5-years. The one-year interval would allow a substantial amount of primary outcome data to accumulate and compare to the retrospective data already collected. The three- and five-year intervals would allow an ample amount of time for legal action to have taken place regarding sentinel events potentially related to PORB. This data is pertinent because it will highlight the difference in cost-effectiveness between neostigmine and sugammadex related to tremendous litigation fees. At each time interval, the proposed data points will be collected, analyzed, and compared to the retrospective data collected previously which will allow a thorough comparison of neostigmine and sugammadex.

The data would be analyzed by comparing the most recent data to the findings from the initial chart audit. If the recommendations are successful, a reduction should be seen in the OR time, PACU times, and the number of adverse events related to PORB. The collected data should also be analyzed for compliance with the recommendations. A lack of compliance with the recommendations may skew the data to look as if the recommendations have failed. Therefore, the data must be analyzed for compliance before comparing the data to the initial chart audit findings.

Comprehensive Plan for Revisions

Before comparing the initial chart audit and the most recent, recommendation compliance will be investigated to ensure the data will not be skewed. Afterward, if the proposed recommendations are not found to be effective, then the appropriate revisions will be made. If recommendation compliance is not satisfactory, additional education would be provided as well

as following up with providers who are not adhering to the recommendations. If no difference in cost-effectiveness or clinical outcomes is elicited during the conclusion of the one-year interval, the proposed recommendations would be redacted, and provider preference would be encouraged. The project leaders will continue monitoring the 3- and 5- year intervals for possible litigation related to PORB and report any findings.

Dissemination

Utilizing the extensive literature search, the project leaders will compose a poster presentation highlighting the synthesized literature along with the plan for enactment, monitoring, and adjustments. The dissemination will involve the project team members, key stakeholders, faculty staff, and scholarly peers. Relevant background information will be presented by the project leaders along with why this topic is of importance. Subsequently, a concise but thorough literature review will be presented highlighting the most evidence-based practice recommendations. Lastly, a plan that includes enactment, monitoring, and adjustment will be displayed that details how the project can be rolled out at a facility.

Conclusion

The literature search confirmed patients with OSA are more susceptible to PPCs related to residual neuromuscular blockade. Currently, evidence-based recommendations are minimal, if not absent, to guide NMBA reversal in patients with OSA. A synthesis of the literature concluded that sugammadex is associated with a reduced incidence of PPCs in patients with OSA. The significant cost of a PPC can be avoided by using sugammadex in this patient population. After a thorough literature search, the project team concluded all surgical patients should be screened for OSA prior to their procedure. Patients previously diagnosed with OSA or demonstrated to be at risk for OSA by a STOP-Bang score greater than 3 should be reversed with

sugammadex if they received rocuronium or vecuronium. However, more research is needed before recommendations can be made for the uninhibited use of sugammadex in all populations.

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Appendix A

Levels of Evidence Synthesis Table

Citation (Author, Year, Title, etc…)	Conceptual Framework (Theoretical basis for study)	Design/ Method	Sample/Setting (Number, Characteristics, Exclusions, Criteria, Attrition, etc…)	Major Variables; definitions (Independent variables; Dependent variables)	Outcome Measurement (What scales used – reliability information – alphas)	Data Analysis (What stats used?)	Findings (Statistical findings or qualitative findings)	Level of Evidence Level =	Quality of Evidence Strength Limits Risks Feasibility
Article 1: Postoperative complications with neuromuscular blocking drugs and/or reversal agents in obstructive sleep apnea patients: A systematic review									
See below	Not evident	Systematic Review	Out of 4123 studies, five studies (2 RCTs and 3 observational studies) were deemed eligible.	Patients who were given NMBD and/or NMBD reversal agents intraoperatively; risk of postoperative complications from the use of NMBD than non-OSA patients	Risk of developing postoperative pulmonary complications (PPCs) like hypoxemia, residual neuromuscular blockade, or respiratory failure compared to non-OSA patients	Incidence of PORC, adverse events with sugammadex, and neostigmine	OSA patients who received intraoperative NMBD may be at higher risk for postoperative residual neuromuscular blockade, hypoxemia, and respiratory failure. The use of sugammadex was associated with less postoperative pulmonary complications in patients with OSA as compared to neostigmine, however, the evidence was very limited as the studies were of low to moderate quality	I	Quality of evidence is strong. Literature is composed of the highest level of evidence; systematic review
Article 2: Comparison of Sugammadex versus Neostigmine Costs and Respiratory Complications in Patients with Obstructive Sleep Apnoea									
See below	Not evident	RCT	74 patients in ASA I or II were	Time to TOF 0.9, operating room time, PACU stay,	Time of TOF, operating room		This study confirmed the efficacy of sugammadex over	III	

			randomized into two groups to receive 2 mg/kg sugammadex (Group S) or 0.04 mg/kg Neostigmine with 0.5mg atropine (Group N)	postoperative respiratory complications, costs related to neuromuscular block reversal and follow-up and treatment complications	time, PACU stay. Reintubations, desaturation was measured. Cost related to anesthesia provider. Cost of reversal drugs. This study confirmed the efficacy of sugammadex over neostigmine for the reversal of rocuronium-induced neuromuscular block. Sugammadex decreases the		neostigmine for the reversal of rocuronium-induced neuromuscular block. Sugammadex decreases the incidence of post-operative respiratory complications and related costs in patients with SA		
Article 3: Effects of sugammadex on incidence of postoperative residual neuromuscular blockade: A randomized, controlled study									
See below	Not evident	RCT	74 patients received sugammadex and 77 patients received usual care (neostigmine/glycopyrrolate). Setting: Massachusetts General Hospital, Boston, MA	Presence of residual muscle blockade, time to operating room discharge-readiness	Zero out of 74 sugammadex patients and 33 out of 76 (43.4%) usual care patients had TOFWatch® SX-assessed residual neuromuscular blockade at PACU admission	Incidence of PORC in PACU	After abdominal surgery, sugammadex reversal eliminated residual neuromuscular blockade in the PACU, and shortened the time from the start of study medication administration to the time the patient was ready for discharge from the operating room	II	Strength: moderate sample size at a large medical hospital. Established primary and secondary endpoints easily identified and measured. Weakness: Timing of reversal agent administration was based on the providers' clinical judgment, allowing room for variability.
Article 4: Influence of reversal of neuromuscular blockade with sugammadex or neostigmine on postoperative quality of recovery following a single bolus dose of rocuronium: A prospective, randomized, double-blinded, controlled study									
See below	Not evident	RCT	Neostigmine (Group N, n = 44) ; sugammadex (Group S, n = 40) ; Setting: University Teaching Hospital from February to July 2017	Quality of recovery and recovery rate of Group S and Group N	The primary endpoint was the effect of sugammadex, compared with neostigmine, on the recovery rate in the physiological domain in patients who underwent PPV with general anesthesia.	Incidence of adverse events after sugammadex and neostigmine	Use of sugammadex may increase the quality of physiological recovery at early postoperative periods, compared with that of neostigmine, following a single	I	Strength: randomized control trial design, patient population was specific in regard to similar ASA status, procedure and dosage given. Weakness: a minimally invasive surgery that has a short duration. Therefore, the study

					The quality of recovery was assessed using the Postoperative Quality Recovery Scale at 15 min and 40 min after surgery and on postoperative day 1		bolus dose of rocuronium in patients undergoing PPV with general anesthesia		outcome may not be applicable to a larger population undergoing different types of surgeries. Third, the observation period was short; the assessment of PostopQRS was not performed after postoperative day 1.
Article 5: The Impact of Sleep Apnea on Postoperative Utilization of Resources and Adverse Outcomes									
See below	Not evident	Retrospective study	Analyzed hospital discharge data of patients who underwent total hip or knee arthroplasty in approximately 400 U.S. Hospitals between 2006 and 2010. 530,089 entries for patients undergoing total hip and knee arthroplasty. Of those, 8.4% had a diagnosis code for SA.	Diagnosis of OSA. pulmonary and cardiac complications	Adverse events related to sleep apnea	Incidence of postoperative complications with and without SA	Pulmonary complications were 1.86 (95% CI, 1.65–2.09) times more likely, and cardiac complications 1.59 (95% CI, 1.48–1.71) times more likely to occur in patients with SA. In addition, SA patients were more likely to receive ventilatory support, use more intensive care, step-down and telemetry services, consume more economic resources and have longer lengths of hospitalization	IV	Strength: L arge volume of data Limits: Retrospective study, unable to control variables.
Article 6:	Postoperative complications associated with obstructive sleep apnea: time to wake up!								
See below	Not evident	Retrospective Cohort Study	Included: Patients greater than 18 years of age, diagnosed preoperatively with OSA, and scheduled to undergo elective surgery Excluded: Patients who were undergoing surgical procedures involving	The primary variable was the incidence of postoperative complications	The incidence of postoperative complications and related treatments were compared between the OSA patients and the matched non-OSA patients	Demographic data (including gender and age at the time of surgery), ASA physical status, pre-existing medical conditions, concurrent medications, type of surgery and anesthesia, postoperative	The incidence of postoperative complications in the OSA patients was 44% vs 28% in the non-OSA group	IV	Limit: Patients with OSA were identified by using ICD-10 codes which is not all-inclusive of patients with OSA.

			the upper airway, including tonsillectomy, septoplasty, uvuloplasty, uvulopalatoplasty, uvulopharyngoplasty, or uvulopalatopharyngoplasty			complications and therapeutic interventions			
Article 7:	Residual curarization and postoperative respiratory complications following laparoscopic sleeve gastrectomy. the effect of reversal agents: Sugammadex vs. neostigmine								
See below	Not evident	Retrospective study	Patients (179) undergoing laparoscopic sleeve gastrectomy from July 2012 to July 2013 at Wolfson Medical Center	Compared parameters included demographic and anesthetic data, residual curarization, oxyhemoglobin saturation (SpO2) in the recovery room (PACU), episodes of SpO2 lower than 90% in PACU, unexpected intensive care (ICU) admissions, the incidence of atelectasis and pneumonia, reintubation, and duration of hospitalization.	Incidence of PORC and residual block		With the inherent limitations of a retrospective study, the use of sugammadex following laparoscopic sleeve gastrectomy showed no advantage over neostigmine in terms of residual curarization and respiratory complications	IV	Limits: retrospective study, relatively small sample size.
Article 8:	Postoperative Pulmonary Complications' Association with Sugammadex *versus* Neostigmine: A Retrospective Registry Analysis								
See below	Not evident	Retrospective Study	Adult patients from the Vanderbilt University Medical Center database who underwent general anesthesia procedures between January 2010 and July 2019	Block reversed with neostigmine or sugammadex	The primary outcome was postoperative pulmonary complications defined by pneumonia, prolonged mechanical ventilation, and/or unplanned intubation.	An inverse probability of treatment weighting propensity score analysis approach was applied to control for measured confounding	No difference was observed on the odds of postoperative pulmonary complications in patients receiving sugammadex in comparison with neostigmine	IV	Unable to control for the last train of four causing missing data for approximately 40% of patients.
Article 9:	Role of sugammadex in accelerating postoperative discharge: A meta-analysis								

See below	Not evident	Systematic review/Meta-analysis	518 Patients from 6 studies	Time to discharge after NMB reversal with sugammadex or neostigmine	Outcome measurement	Data analysis	Sugammadex was associated with a significantly faster discharge from the OR to the PACU and from the PACU to the surgical ward.	I	Small number of studies included,
Article 10:	Sugammadex versus neostigmine for routine reversal of rocuronium block in adult patients: A cost analysis								
See below	Not evident	Cost analysis	Data from a local hospital system information, meta-analysis of published studies, and the general literature was used to construct base-case scenarios and sensitivity analyses. Analysis performed from the perspective of a single hospital system	No reversal compared to Neostigmine/Glyco reversal compared to Sugammadex reversal	Costs associated with the choice of reversal drug and differences in reversal time, the occurrence of postoperative nausea or vomiting (PONV), and residual blockade requiring unplanned postoperative mechanical ventilation (UPMV)	Cost of the drug compared to OR time, PACU time, and cost of occurrence of adverse events	Cost analysis suggested that reversal with sugammadex is preferable to neostigmine or no reversal drug	VI	Drug costs can vary widely and adverse events were not all inclusive.
Article 11:	Sugammadex versus neostigmine for reversal of neuromuscular blockade and postoperative pulmonary complications (stronger).								
See below	Not evident	Observational matched-cohort study	Adult patients aged 18 yr or older undergoing general anesthesia with an endotracheal tube and receiving a modern steroidal neuromuscular blockade agent (vecuronium or rocuronium) by bolus or infusion with administration of neostigmine or sugammadex were eligible for matching.	Exclusion criteria included age younger than 18 yr; outpatient procedure; emergency, cardiac, liver, or lung transplantation surgery; intubation before operating room arrival; American Society of Anesthesiologists. Physical Status V or VI, denoting a moribund patient or a brain-dead patient undergoing organ procurement;[25] renal failure documented in *International Classification of Diseases, Ninth Revision/Tenth Revision*	Primary outcome was a composite of postoperative pulmonary complications plausibly related to residual neuromuscular blockade.	Rates of (1) pneumonia, (2) respiratory failure, or (3) other major pulmonary complications.	Sugammadex administration was associated with a 30% reduced risk of pulmonary complications, 47% reduced risk of pneumonia and 55% reduced risk of respiratory failure compared to neostigmine.	III	Inherent limitations due to the observational nature of the study, which may warrant a prospective, pragmatic controlled trial

				codes or estimated glomerular filtration rate less than 30 ml/min; sugammadex used in combination with neostigmine; sugammadex or neostigmine use with subsequent redosing of neuromuscular blockade agent, suggestive of temporary neuromuscular blockade reversal for intraoperative neuromonitoring; median intraoperative positive end-expiratory pressure greater than 10 cm H_2O; and institutional use of sugammadex for less than 10% of neuromuscular blockade patients.					
Article 12:									
See below									
Article 13:	Kaw, R., Chung, F., Pasupuleti, V., Mehta, J., Gay, P. C., & Hernandez, A. V. (2012). Meta-analysis of the association between obstructive sleep apnoea and postoperative outcome. *British journal of anaesthesia*, *109*(6), 897–906. https://doi.org/10.1093/bja/aes308								
See below	Not evident	Meta-analysis	Thirteen studies were included in the final analysis (*n*=3942)	restricted to cohort or case–control studies in adult (>18 yr old) patients, with information available on at least one postoperative complication/outcome in patients with and without OSA, published in any language	primary postoperative outcomes were any cardiac or respiratory complications. Postoperative respiratory complications were characterized as postoperative desaturation, acute respiratory failure (ARF), and tracheal reintubation.	The incidence of postoperative desaturation, respiratory failure, postoperative cardiac events, and ICU transfers was higher in patients with OSA.	OSA was also significantly associated with higher odds of desaturation. OSA was associated with significantly higher odds of any postoperative cardiac events	I	Weakness: restricted to cohort or case-control studies only

Article 14:	Fernandez-Bustamante, A., Frendl, G., Sprung, J., Kor, D. J., Subramaniam, B., Martinez Ruiz, R., Lee, J. W., Henderson, W. G., Moss, A., Mehdiratta, N., Colwell, M. M., Bartels, K., Kolodzie, K., Giquel, J., & Vidal Melo, M. F. (2017). Postoperative Pulmonary Complications, Early Mortality, and Hospital Stay Following Noncardiothoracic Surgery: A Multicenter Study by the Perioperative Research Network Investigators. *JAMA surgery*, *152*(2), 157–166. https://doi.org/10.1001/jamasurg.2016.4065								
See below	Not evident	multicenter prospective observational study	7 US academic institutions. American Society of Anesthesiologists physical status 3 patients who presented for noncardiothoracic surgery requiring 2 hours or more of general anesthesia with mechanical ventilation from May to November 2014 were included in the study	noncardiothoracic surgery requiring 2 hours or more of general anesthesia with mechanical ventilation	Predefined PPCs occurring within the first 7 postoperative days were prospectively identified. We used bivariable and logistic regression analyses to study the association of PPCs with ventilatory and other perioperative variables.		Postoperative pulmonary complications are common in patients with American Society of Anesthesiologists physical status 3, despite current protective ventilation practices. Even mild PPCs are associated with increased early postoperative mortality, ICU admission, and length of stay (ICU and hospital). Mild frequent PPCs (eg, atelectasis and prolonged oxygen therapy need) deserve increased attention and intervention for improving perioperative outcomes	3	Weakness: observational studies Strength: 7 academic institutions
Article 15:	Fleisher, L. A., & Linde-Zwirble, W. T. (2014). Incidence, outcome, and attributable resource use associated with pulmonary and cardiac complications after major small and large bowel procedures. *Perioperative Medicine*, *3*(1). https://doi.org/10.1186/2047-0525-3-7								
See below	Not evident	Retrospective study	45,969 discharges in patients undergoing major bowel procedures	45,969 discharges in patients undergoing major bowel procedures.	Premier database to determine the incidence and direct medical costs related to pulmonary complications and compared it to cardiac complications in the same cohort.	current study demonstrates that postoperative pulmonary complications represent a significant source of morbidity and incremental cost after major small intestinal and colon surgery and have greater incidence and costs than	Postoperative pulmonary complications (PPC) or postoperative cardiac complications (PCC) were present in 22% of cases; PPC alone was most common (19.0%), followed by PPC and PCC (1.8%) and PCC alone (1.2%). The incremental cost of PPC is large	3	Weakness: level of evidence Strength: large sample

						cardiac complications alone. Therefore, strategies to reduce the incidence of these complications should be targeted as means of improving health and bending the cost curve in health care.	($25,498). In comparison, PCC alone only added $7,307 to the total cost.		
Article 16:	Carron, M., Baratto, F., Zarantonello, F., & Ori, C. (2016). Sugammadex for reversal of neuromuscular blockade: A retrospective analysis of clinical outcomes and cost-effectiveness in a single center. *ClinicoEconomics and Outcomes Research*, 43. https://doi.org/10.2147/ceor.s100921								
See below	Not evident	Retrospective analysis	five operating rooms at University Hospital of Padova, surgical patients receiving rocuronium/sugammadex	Patients undergoing general anesthesia with NMB who received sugammadex for "preventive" use were 3% of the total cases (128 of 4,282 [total cases]		cost-analysis of NMB management accompanying the introduction of a rocuronium–neostigmine–sugammadex strategy into a cisatracurium–neostigmine regimen was carried out. To such purpose, two periods were compared: 2011–2012, without sugammadex available; 2013–2014, with sugammadex available. A subsequent analysis was performed to evaluate if sugammadex replacing neostigmine as first choice reversal drug is cost-effective.	sugammadex promotes a rapid turnover of patients in the OR, which is cost-effective and limits the disadvantage of its high cost. Through a rapid, predictable, and safe reversal of rocuronium-induced NMB, sugammadex minimizes the risk of PORC and its consequences.	3	Weakness: Retrospective analysis Strength: large sample
Article 17:	Impact of sugammadex versus neostigmine/glycopyrrolate on perioperative efficiency								

See below	Not evident	Retrospective study	Patients admitted to Houston Methodist Hospital with a performed surgical procedure Exclusions: neurosurgical or cardiac catheterization procedure, reversal agent administration within the PACU, extubation prior to reversal agent administration or procedure completion, sugammadex reversal of cisatracurium or succinylcholine, non-recorded pre-PACU/post reversal agent train-of-four, zero-minute time difference from procedure start or completion to reversal agent administration, missing endpoint documentation, and reversal with both sugammadex and neostigmine/glycopyrrolate	Neuromuscular blocker agent administration to exit from OR and PACU times	Cost-effective analysis	The Shapiro–Wilk normality test dictated nonparametric analysis of continuous data with the Wilcoxon rank-sum test or Mann–Whitney U-test. The chi-squared test or Fisher's exact test was utilized for the analysis of categorical variables.	Sugammadex administration does not correlate to meaningful time saved in the OR	IV	Limits: small population of 257, only considered cost in relation to OR time

Article 1:
Hafeez, K., Tuteja, A., Singh, M., Wong, D. T., Nagappa, M., Chung, F., & Wong, J. (2018). Postoperative complications with neuromuscular blocking drugs and/or reversal agents in obstructive sleep apnea patients: A systematic review. BMC Anesthesiology, 18(1). https://doi.org/10.1186/s12871-018- 0549-x

Article 2:
Yazicioglu Unal, D., Baran, I., Mutlu, M., Ural, G., Akkaya, T., & Ozlu, O. (2020). Comparison of sugammadex versus neostigmine costs and respiratory complications in patients with obstructive sleep apnoea. *Turkish Journal of Anaesthesiology and Reanimation*, *43*(6), 387–395. https://doi.org/10.5152/tjar.2015.35682

Article 3:
Brueckmann, B., Sasaki, N., Grobara, P., Li, M., Woo, T., de Bie, J., Maktabi, M., Lee, J., Kwo, J., Pino, R., Sabouri, A., McGovern, F., Staehr-Rye, A., & Eikermann, M. (2015). Effects of sugammadex on incidence of postoperative residual neuromuscular blockade: A randomized, controlled study. *MEDLINE*. https://doi.org/10.1093/bja/aev104

Article 4:

Kim, N., Koh, J., Lee, K.-Y., Kim, S., Hong, J., Nam, H., & Bai, S.-J. (2019). Influence of reversal of neuromuscular blockade with sugammadex or neostigmine on postoperative quality of recovery following a single bolus dose of rocuronium: A prospective, randomized, double-blinded, controlled study. *Journal of Clinical Anesthesia*, *57*, 97–102. https://doi.org/10.1016/j.jclinane.2019.02.014

Article 5:

Memtsoudis, S. G., Stundner, O., Rasul, R., Chiu, Y.-L., Sun, X., Ramachandran, S.-K., Kaw, R., Fleischut, P., & Mazumdar, M. (2014). The impact of sleep apnea on postoperative utilization of resources and adverse outcomes. *Anesthesia & Analgesia*, *118*(2), 407–418. https://doi.org/10.1213/ane.0000000000000051

Article 6:

Chung F, Mokhlesi B. Postoperative complications associated with obstructive sleep apnea: time to wake up! Anesth Analg. 2014;118:251–3.

Article 7:

Ezri, T., Evron, S., Petrov, I., Schachter, P., Berlovitz, Y., & Shimonov, M. (2015). Residual curarization and postoperative respiratory complications following laparoscopic sleeve gastrectomy. the effect of reversal agents: Sugammadex vs. neostigmine. *The Journal of Critical Care Medicine*, *1*(2), 61–67. https://doi.org/10.1515/jccm-2015-0009

Article 8:

Li, G., Freundlich, R. E., Gupta, R. K., Hayhurst, C. J., Le, C. H., Martin, B. J., Shotwell, M. S., & Wanderer, J. P. (2021). Postoperative pulmonary complications' association with sugammadex versus neostigmine: A retrospective registry analysis. *Anesthesiology*, *134*(6), 862–873. https://doi.org/10.1097/aln.0000000000003735

Article 9:

Carron, M., Zarantonello, F., Lazzarotto, N., Tellaroli, P., & Ori, C. (2017). Role of sugammadex in accelerating postoperative discharge: A meta-analysis. *EBSCO*. https://doi.org/10.1016/j.jclinane.2017.03.004

Article 10:

Hurford, W. E., Welge, J. A., & Eckman, M. H. (2020). Sugammadex versus neostigmine for routine reversal of rocuronium block in adult patients: A cost analysis. *ScienceDirect*. https://doi.org/10.1016/j.jclinane.2020.110027

Article 11:

Kheterpal, S., Vaughn, M. T., Dubovoy, T. Z., Shah, N. J., Bash, L. D., Colquhoun, D. A., Shanks, A. M., Mathis, M. R., Soto, R. G., Bardia, A., Bartels, K., McCormick, P. J., Schonberger, R. B., & Saager, L. (2020). Sugammadex versus neostigmine for reversal of neuromuscular blockade and postoperative pulmonary complications (stronger). *Anesthesiology*, *132*(6), 1371–1381. https://doi.org/10.1097/aln.0000000000003256

Article 12:

Miskovic, A. B. Lumb, Postoperative pulmonary complications, *BJA: British Journal of Anaesthesia*, Volume 118, Issue 3, March 2017, Pages 317–334, https://doi.org/10.1093/bja/aex002

Article 13:

Kaw, R., Chung, F., Pasupuleti, V., Mehta, J., Gay, P. C., & Hernandez, A. V. (2012). Meta-analysis of the association between obstructive sleep apnoea and postoperative outcome. *British journal of anaesthesia*, *109*(6), 897–906. https://doi.org/10.1093/bja/aes308

Article 14:

Fernandez-Bustamante, A., Frendl, G., Sprung, J., Kor, D. J., Subramaniam, B., Martinez Ruiz, R., Lee, J. W., Henderson, W. G., Moss, A., Mehdiratta, N., Colwell, M. M., Bartels, K., Kolodzie, K., Giquel, J., & Vidal Melo, M. F. (2017). Postoperative Pulmonary Complications, Early Mortality, and Hospital Stay Following Noncardiothoracic Surgery: A Multicenter Study by the Perioperative Research Network Investigators. *JAMA surgery*, *152*(2), 157–166. https://doi.org/10.1001/jamasurg.2016.4065

Article 15:

Fleisher, L. A., & Linde-Zwirble, W. T. (2014). Incidence, outcome, and attributable resource use associated with pulmonary and cardiac complications after major small and large bowel procedures. *Perioperative Medicine*, *3*(1). https://doi.org/10.1186/2047-0525-3-7

Article 16:

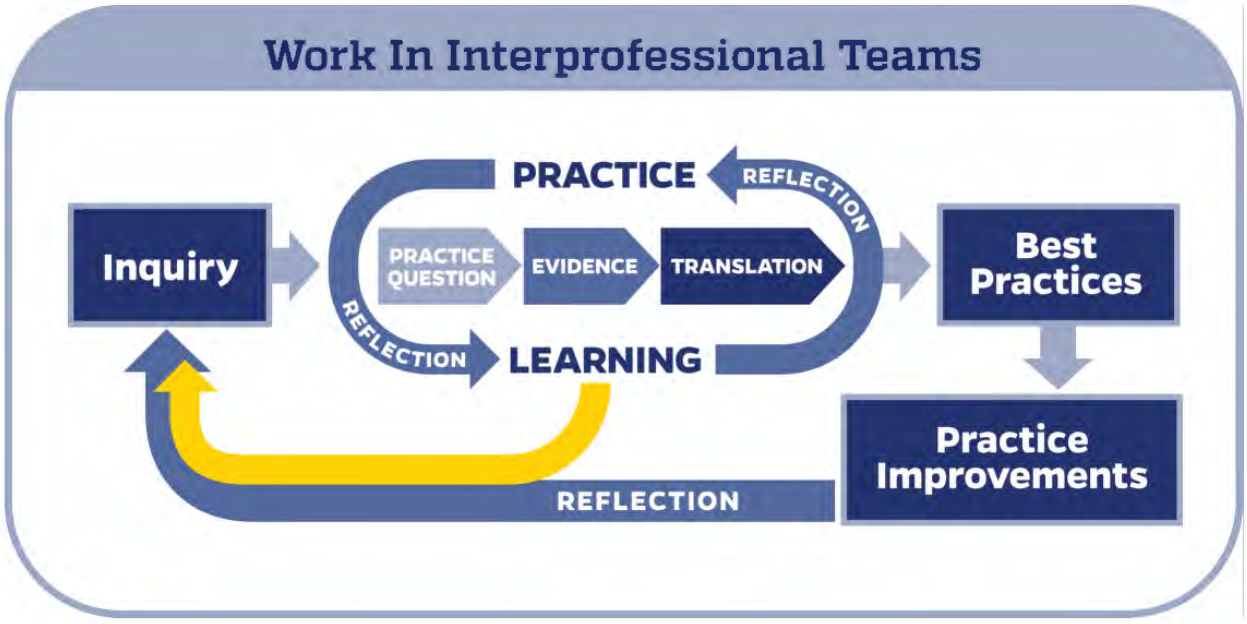
Carron, M., Baratto, F., Zarantonello, F., & Ori, C. (2016). Sugammadex for reversal of neuromuscular blockade: A retrospective analysis of clinical outcomes and cost-effectiveness in a single center. *ClinicoEconomics and Outcomes Research*, 43. https://doi.org/10.2147/ceor.s100921

Article 17:

Deyhim, N., Beck, A., Balk, J., & Liebl, M. (2020). Impact of sugammadex versus neostigmine/glycopyrrolate on perioperative efficiency. *ClinicoEconomics and Outcomes Research*, *Volume 12*, 69–79. https://doi.org/10.2147/ceor.s221308

Appendix B

Johns Hopkins Evidence-Based Practice Model



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Appendix C
Otterbein University
IRB Exemption Statement

Conversation between IRB Chair, Dr. Noam Shpancer and Dr. John Chovan, Department of Nursing Chair.

From: Shpancer, Noam <nshpancer@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:44 AM
To: Chovan, John <jchovan@otterbein.edu>
Subject: Re: IRB and DNP Projects

John: The way I see it, a project is not subject to IRB review unless and until it collects data from human participants. So, I agree with you that these projects will not need IRB approval until someone decides to implement them for data collection, at which point that person may apply for IRB approval.

Thanks, Noam.
From: Chovan, John <jchovan@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:10 AM
To: Shpancer, Noam <nshpancer@otterbein.edu>
Subject: IRB and DNP Projects

Good morning, Noam,

I could use some advice -- maybe a conversation -- about the Doctor of Nursing Practice final scholarly projects and submitting for IRB approval. The projects parameters from our accreditors for some of the projects have changed. The list of acceptable projects now includes the option of writing a plan for a project that is not implemented. So, it can effectively stop at the proposal stage, and then these projects can be available for a future student to implement if someone has that interest. I have at least two questions.

1. The IRB Guidelines states "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Most of these projects are not intended to develop or contribute to generalizable knowledge. They are clinical change projects that are intended to eventually change a clinical practice of health care professionals (humans) in one identified setting. They have the possibility of contributing to generalizable knowledge in that each would be an instance of a clinical change that, if implemented in other places by others, could eventually be generalized. But that is not the primary intent of the projects. Would they be considered research? I think they would not.

2. If indeed they are considered research and should be submitted for review by the IRB, at what point in the process should IRB approval be obtained? I would think that although implementation is not part of the initial project, review by IRB would be helpful to the original team in shaping their project plan. Yet if this proposal is not going to be implemented, then the approval to move forward would be moot. But if a second team eventually reads the proposal and wants to implement it, would they be the ones seeking IRB approval?

If you would prefer that we talk in real time, I am open to that. Or perhaps you could visit one of our faculty meetings for a discussion?

Thank you.

Best,

John

John D. Chovan, PhD, DNP, RN, CNP, CNS, PMHNP-BC
Associate Professor & Chair, Department of Nursing
Chief Nurse Administrator
Otterbein University

"A comprehensive institution with a strong liberal arts base"
jchovan@otterbein.edu; 614-823-1526, voice; he/him/his
"The world is starved for grace. If we are going to work at restoring fellowship and reaching people, we need grace now more than ever."
- Pastor John Swadley, Forest Park Baptist Church, Joplin, Missouri

Appendix D

RECOMMENDATIONS FOR REVERSAL OF ROCURONIUM AND VECURONIUM IN PATIENTS AT RISK FOR OR DIAGNOSED WITH OBSTRUCTIVE SLEEP APNEA

CURRENT PRACTICE

- ☐ Neostigmine and glycopyrrolate are used to reverse rocuronium and vecuronium in all patients while sugammadex is reserved for emergency use.

RECOMMENDATION #1

Every surgical patient should be screened for obstructive sleep apnea with the STOP-Bang screening tool during the pre-operative period.

- ☐ Many patients with obstructive sleep apnea remain undiagnosed at the time of surgery.
- ☐ It is important to identify these patients early in the perioperative experience so that they can be treated and monitored appropriately.

RECOMMENDATION #2

A patient identified as at risk for obstructive sleep apnea, as identified by a STOP-Bang score greater than 3, or with a previous diagnosis of sleep apnea should be reversed with sugammadex.

- ☐ There is a higher incidence of pulmonary complications for patients with obstructive sleep apnea. However, there are fewer postoperative complications associated with these patients when reversed with sugammadex.
- ☐ The dosing of sugammadex should follow the manufacturer's guidelines.

RECOMMENDATION #3

If patient scores less than 3 on STOP Bang scale, choice of reversal agent should be deferred to clinician judgement with consideration of other patient comorbidities.

- ☐ Although sugammadex is recognized as the superior reversal agent in the literature, its use should not go uninhibited.
- ☐ Patient comorbidities should be evaluated and the risk and benefit of administering sugammadex or neostigmine should be performed on a case-by-case basis.